REMARKS

The courteous telephone interviews accorded Applicant's undersigned attorney on June 1, 2004 and June 10, 2004 are respectfully acknowledged.

Claims 2, 5-14, 16-19 and 30-31 are cancelled and new claims 42-74 are added. Thus, upon entry of this amendment, claims 1, 3-4, 15, 20-29 and 32-74 are pending. Support for new claims 42-74 is found in original claims 1-41 and the specification. The subject specification addresses the methods of treatment using the otoprotective agents of the invention for treating ototoxicity resulting from exposure to cisplatin and resulting from exposure to noise. In adding a limiting proviso in claims 42, 57 and 71, Applicant merely seeks to exclude the methods of using the otoprotective agents to treat ototoxicity resulting from exposure to cisplatin. This practice is supported by In re Johnson, 558 F.2d 1008. In Johnson, one of the species disclosed in the parent application was the sole count of an interference in which Applicant was not awarded priority. Subsequently, Applicant filed a continuation application with broad claims that excluded the subject matter of the lost count by addition of a proviso. The C.C.P.A. held

> ... that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter." Id. at 1019.

Similarly, by limiting claims 42-74 by proviso, Applicant is merely excising subject matter which was already in the public domain and is not creating an "artificial subgenus" or claiming "new matter." Accordingly, new claims 42-74 are supported by the original claims and specification.

Inherent Anticipation

In the interview of record, the Examiner and the Applicant's attorney discussed the simultaneously submitted unsigned declaration of Dr. Campbell distinguishing the

pending claims from the teachings of Campbell et al. Applicant will supplement the instant amendment with a signed declaration of Dr. Campbell. The Examiner recognized the merit of the arguments presented by Applicant's attorney distinguishing the pending claims from the teachings of Campbell et al. However, the Examiner stated that the claims lack novelty over that reference because a subset of those receiving cisplatin in chemotherapy would also have been exposed to noise that would have caused ototoxicity, so that the claims are inherently anticipated by the prior art administration of D-methionine for treatment of cisplatin-induced ototoxicity. The Examiner therefore stated that, to establish novelty, it would be necessary to add a proviso to the claims excluding treatment of those suffering from noise-induced ototoxicity who also receive both cisplatin and D-methionine as described in Campbell et al. It is Applicant's understanding that, if the Examiner is satisfied that there is support in the specification for such a proviso, and the claims are amended to include the proviso, the claims would be deemed allowable.

Subsequently to the interview, Applicant has further reviewed Campbell et al., Hearing Research 102 (1996) 90-98, and respectfully submits that this reference does not inherently anticipate claims 1, 3-4, 15, 20-29 and 32-41. Campbell et al. disclose the treatment of five groups of rats. These groups were an untreated control, a treated control (16 mg/kg cisplatin), and three treated experimental groups ((1) 75 mg/kg D-methionine + 16 mg/kg cisplatin; (2) 150 mg/kg D-methionine + 16 mg/kg cisplatin; and (3) 300 mg/kg D-methionine + 16 mg/kg cisplatin). Campbell et al. do not address any other cause of ototoxicity except that from cisplatin. In addition, D-methionine was not used to treat human patients; rats were the experimental subjects.

The Office has asserted that there would inherently be a subset of those patients exposed to cisplatin as described in Campbell et al., that were also exposed to ototoxicity-inducing noise. However, inherency may not be established if there is only a probability or possibility that a certain result may occur. In re Oelrich, 666 F.2d 578. There is no disclosure by Campbell et al. that shows that any of the rats in any of the

five groups were exposed to a level of noise that would cause ototoxicity. Moreover, a person of ordinary skill would know when evaluating the disclosure by Campbell et al. that in order to reduce the number of variables, the experiments would be designed to eliminate the possibility that the rats would be exposed to an ototoxic level of noise or indeed, to expose the rats to any significant level of noise. Accordingly, Campbell et al. do not disclose any facts which would make it more than a possibility that a subset of rats exposed to both an ototoxic level of cisplatin and an ototoxic level of noise would exist and thus, claims 1, 3-4, 15, 20-29 and 32-41 are not anticipated by Campbell et al.

As explained by Applicant's undersigned attorney during the telephone interview of June 1, 2004, Applicant is not aware of any clinical testing of D-methionine vs. cisplatin-induced ototoxicity either before Applicant's invention or more than a year prior to the instant application. Even if a basis for inherency could have been established by clinical tests on human subjects, a proposition that would seem doubtful at best under the authority of Oelrich, there is unquestionably no basis for inherency of noise-induced ototoxicity in the laboratory rats selected for the tests described in the Hearing Research article.

New Claims 42-74

Although it is believed that claims 1-41 patentably distinguish the art of record, Applicant further presents new claims 42-74 which are also submitted to distinguish Campbell et al. Claim 42 is directed to a method for preventing or treating a patient exposed to noise for a time and at an intensity sufficient to result in ototoxicity by administering an effective amount of an otoprotective agent comprising a compound containing a methionine or a methionine-like moiety, provided that, at the time said otoprotective agent is administered, an antineoplastic dose of cisplatin has not been prescribed for administration to said patient. Even if it is more than a probability or possibility that a subset of rats exposed to both an ototoxic level of cisplatin and an ototoxic level of noise would exist, claim 42 is not anticipated by Campbell et al due to

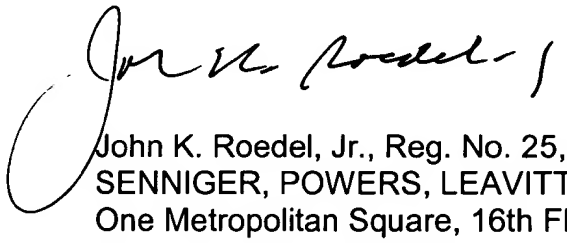
the express requirement that "at the time said otoprotective agent is administered, an antineoplastic dose of cisplatin has not been prescribed for administration to said patient." This proviso definitively distinguishes Campbell et al., wherein 16 mg/kg cisplatin was prescribed for administration 30 minutes after administration of various dosages of D-methionine. Accordingly, claims 42-74 are not anticipated by Campbell et al.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

A check in the amount of $1,398.00 ($740.00 for a four month extension; $273.00 for 9 additional dependent claims and 3 additional independent claims; and $385.00 for the Request for Continued Examination). The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,



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